REMARKS

In the Office Action dated November 2, 2005, the Examiner rejected pending claims 48-53 and 55-60 under 35 U.S.C. § 112, first paragraph, as allegedly containing new subject matter not present in the specification as originally filed. The Examiner further rejected claims 48-53, 55, and 57-60 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. The Examiner further rejected claims 48-53 and 55-60 under 35 U.S.C. § 102(b), as allegedly being anticipated by the Plested et al reference (Infect Immun. 1999 Oct; 67(10): 5417-26). The Examiner refused to grant priority to the subject claims from U.S. Provisional Applications 60/196,305, filed 4/12/00, and 60/156,940, filed 09/30/99, alleging that the subject claims lack descriptive support in Provisional Applications 60/196,305 and 60/156,940. Thus, Plested, although published after U.S. Provisional Application 60/156,940, was used as a prior art reference under 35 U.S.C. § 102(b).

In a Response dated March 1, 2006 to the pending Office Action, Applicants filed an amended set of claims and an explanation of why the pending set of claims is allowable. Applicants' arguments included an explanation of how the full range of embodiments covered by the pending claims was enabled by the specification of the subject application.

In an Advisory Action dated March 14, 2006, the Examiner maintained the 35 U.S.C. § 112, first paragraph rejection of claims 48, 49, 55, and 46 on the grounds that this rejection is a new matter rejection, not an enablement rejection. The Examiner further alleged that the 35 U.S.C. § 112, first paragraph issue with the pending claims is not the antigenicity or epitope reactivity of all Neisseria strains containing the conserved epitope (or of *N. meningitidis* immunotypes L1, L3, L7, L8, L9, L10, L11, and L12) with monoclonal antibody B5. Rather, the Examiner alleged that the subject application lacks descriptive support for the claimed method, as described in detailed in the Claims Rejections section hereinbelow.

The Examiner further maintained the rejection of claims 48, 49, 55, and 56 under 35 U.S.C. § 102(b) in view of Plested. As a result of the new matter issues described above, the Examiner refused to grant priority to the subject claims to U.S. Provisional Applications 60/196,305 and 60/156,940. Thus, Plested was maintained as an allegedly anticipatory reference under 35 U.S.C. § 102(b).

The Examiner admitted, however, that the other grounds for rejection cited in the Final Office Action dated November 2, 2005 did not apply to the amended set of claims filed on March 1, 2006.

The Amendment dated March 1, 2006 was not entered.

Thus, the only remaining issues with the pending set of claims filed on March 1, 2006 are (a) the new matter rejection of claims 48, 49, 55, and 56 under 35 U.S.C. § 112, first paragraph and (b) the 35 U.S.C. § 102(b) rejection in view of Plested. The present Response is intended to be fully responsive to these 2 remaining issues and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

Status of Claims

Claims 48-53 and 55-60 were pending in the application. Claims 48-53 and 55-60 have been rejected. Claims 48 and 55 have herein been amended.

Claims 50-53 and 57-60 have herein been canceled without prejudice or disclaimer. In making this cancellation without prejudice, Applicants reserve all rights in these claims to file divisional and/or continuation patent applications.

CLAIM REJECTIONS

35 U.S.C. § 112 Rejections

In the Office Action, the Examiner rejected claims 48-53 and 55-60 under 35 U.S.C. § 112, first paragraph, as allegedly containing new matter not containing in the specification as filed. Further, the Examiner alleged that the subject application lacks descriptive support for the administration of any "immunogenic composition comprising an inner core of a *Neisseria* LPS, wherein a PEtN moiety is linked to position 3 of a HepII moiety of the inner core," wherein the composition, upon administration to a host, elicits an antibody that recognizes all *N. meningitidis* immunotypes L1, L3, L7, L8, L9, L10, L11, and L12. Further, the Examiner

alleged that the only immunogenic composition disclosed in the subject specification is a *galE* mutant of *N. meningitidis*. Thus, the Examiner alleged that the subject specification does not provide descriptive support for the claimed method of use, utilizing any immunogenic composition comprising an inner core of a *Neisseria* LPS, wherein a PEtN moiety is linked to position 3 of a HepII moiety of the inner core.

Applicants respectfully disagree. Contrary to the Examiner's assertions, the subject specification is directed to a vaccine comprising a ***conserved epitope***, wherein the epitope is defined by the presence of PEtN at the 3-position of Hep2 of the inner core. The *galE N. meningitidis* mutant was utilized in the subject specification ***not*** as a principal embodiment of the vaccines of the subject invention, but rather as a ***means*** to elicit monoclonal antibody B5, which in turn was used as a means to define the conserved epitope central to vaccines of the present invention:

> "The ***epitope against which B5 reacts*** has been characterized and ***can be used to form the basis of a vaccine*** to prevent *Neisseria* infections" (page 6, third full paragraph; emphasis added).

Thus, contrary to the Examiner's allegations, the vaccines of present invention are defined by the presence of the conserved epitope, not by the *galE* mutation.

Further, the subject specification clearly defines the conserved epitope as being characterized by the presence of PEtN at the 3-position of Hep2 of the inner core:

> "The immunogenic component of the present invention is typically only limited by the requirement for a PEtN moiety linked to the 3-position of HepII of the inner core" (page 9, fifth paragraph).

> "Critical to the epitope of strains recognized by the monoclonal antibody B5 is a PEtN on the 3-position of the ?-chain HepII (Figure 1)" (page 21, third paragraph).

Further, the subject specification describes administration of vaccines comprising the conserved epitope for prevention of *Neisseria* infections:

> "The present invention also relates to a method for the prevention of *Neisseria* infection, the method comprising administering to a subject a need of such treatment an effective amount of a vaccine as described above" (page 15, fifth full paragraph).

A person of ordinary skill in the art would recognize that prevention of *Neisseria* infection by a vaccine would only occur if the vaccine elicited antibodies that recognize the target *Neisseria* strain.

Further, the claims of the subject specification as filed describe a vaccine comprising a ***conserved epitope***, wherein the epitope is defined by the presence of PEtN at the 3-position of Hep2 of the inner core, and its use in eliciting antibodies against a wide range of *Neisseria* strains:

> 1. A vaccine for the treatment of disease caused by pathogenic *Neisseria*, the vaccine comprising an immunogenic component based on the inner core of a *Neisseria* lipopolysaccharide, LPS, and being capable of eliciting functional antibodies against a majority of the strains within the species of the pathogenic *Neisseria*.

> 10. A vaccine according to claim 1, **wherein the immunogenic component is an epitope on the LPS inner core characterized by the presence of a phosphoethanolamine moiety linked to the 3-position at HepII of the inner core**, or is a functional equivalent thereof. (emphasis added).

Thus, the subject specification describes administration of a vaccine comprising a conserved epitope, defined by the presence of PEtN at the 3-position of Hep2 of the inner core, for elicitation of antibodies that recognize *Neisseria*.

Further, the subject specification clearly defines the *Neisseria* strains that are recognized by vaccines of the present invention:

> "An inner core structure recognized by MAb B5 is conserved and accessible in 26/34 (76%) of Group B and 78/112 (70%) of Groups A, C, W, X, Y, and Z

> strains. *Neisseria meningitidis* strains which possess this epitope are immunotypes in which PEtN is linked to the 3-position of the ?-chain HepII of the inner core" (page 21, first paragraph).
>
> "Of the 12 immunotypes, MAb B5 recognized the LPS of strains in which the inner core oligosaccharide has a PEtN linked to the 3-position of HepII (Table 2 and Figure 1). Thus, immunotypes L2, L4, L6 did not react with MAb B5, whereas immunotypes L1, L3, L7-12 were recognized by MAb B5" (page 31, second full paragraph).

Accordingly, the subject specification describes a method of eliciting an antibody that recognizes all *N. meningitidis* immunotypes L1, L3, L7, L8, L9, L10, L11, and L12, comprising administration of any vaccine comprising the conserved epitope, wherein the conserved epitope is defined by the presence of PEtN at the 3-position of Hep2 of the inner core.

Thus, the subject matter of the pending claims was clearly described in the subject specification as filed. Applicants therefore respectfully request that the rejection be withdrawn.

The Examiner further alleged that support in the subject specification for immunogenic compositions was limited to compositions derived from *N. meningitidis* inner core, to the exclusion of other *Neisseria* species.

Applicants respectfully disagree. The subject specification clearly describes that the immunogenic component can be derived from *Neisseria* species other than *N. meningitidis*:

> "The invention also extends to immunogenic components in other Neisseria species which are related to those identified in *N. meningitidis*, either by function, antibody reactivity or structure. The invention is not limited to pathogenic strains of *Neisseria*. The vaccine of this invention can be derived from a commensural strain of *Neisseria*" (paragraph beginning on page 10).
>
> Applicants therefore respectfully request that the rejection be withdrawn.

In summary, the subject specification as filed describes a method of eliciting an antibody that recognizes all *N. meningitidis* immunotypes L1, L3, L7, L8, L9, L10, L11, and L12, comprising administration of any vaccine comprising the conserved epitope, wherein the conserved epitope is defined by the presence of PEtN at the 3-position of Hep2 of the inner core. The conserved epitope may be derived from any *Neisseria* species. Thus, the pending claims contain new matter over the subject specification as filed, and therefore are in compliance with the requirements of 35 U.S.C. § 112.

35 U.S.C. § 102 Rejections

Further, the Examiner maintained the rejection of claims 48, 49, 55, and 56 under 35 U.S.C. § 102(b) in view of Plested. As a result of the new matter issues described above, the Examiner refused to grant priority to the subject claims to U.S. Provisional Applications 60/196,305 and 60/156,940. Thus, Plested was maintained as an allegedly anticipatory reference under 35 U.S.C. § 102(b).

As described hereinabove, the pending claims of the subject application contain no new matter over the subject specification as filed. Thus, it is improper to use Plested as an anticipatory reference against the subject specification under 35 U.S.C. § 102(b).

Applicants therefore respectfully request that the rejection be withdrawn.

In view of the foregoing amendments and remarks, the pending claims are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number below. Similarly, if there are any further issues yet to be resolved to advance the prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

Please charge any fees associated with this paper to deposit account No. 50-3355.

Respectfully submitted,

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